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5/25/98

U.S. Food and Drug Administration
New York District
850 Third Avenue, Brooklyn, New York 11232-

Telephone: (718) 340-7000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 7, 1998

George Braff, M.D.
Cumberland Diagnostic & Treatment Center
100 North Portland Avenue
Brooklyn, New York 11205

Re: 27-NYK-98

Dear Dr. Braff:

Your facility was inspected on April 15, 1998 by a representative of the New York City Bureau of Radiological Health, under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The interpreting physicians, Dr. [redacted] and Dr. [redacted], did not meet the requirements of being board certified by any of the approved boards or having two months full time training in the interpretation of mammograms.

The specific deficiencies noted above appeared under the Level 1 heading of your MQSA Facility Inspection Report, which was issued after the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response must address the Level 2 noncompliances that were listed on the inspection report provided to you after the close of the inspection. These Level 2 noncompliances are:

The interpreting physicians, Drs. [redacted] and [redacted], did not meet the initial training requirement of having 40 hours of continuing medical education in mammography;

The interpreting physicians, Drs. [redacted] and [redacted] did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months;

Drs. [redacted], and [redacted] did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months;

The interpreting physician, Dr. [redacted] did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3 year period (an average of 5 credits/year).

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies that the inspection identified and promptly initiate corrective action.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspend or revoke a facility's FDA certificate for failure to comply with the Standards; seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude the City from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent City requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of: the specific steps you have taken to correct the violations noted in this letter; each step your facility is taking to prevent recurrences of similar violations; and submit records that demonstrate the interpreting physicians' qualifications, if such records exist.

If your facility is unable to provide the requested documentation within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Please send the original copy of your response to me at the above address, and a copy to Mr. Murray L. Kurzman of my staff, at US Food and Drug Administration, 6800 Jericho Turnpike., Suite 109E, Syosset, NY 11791. Also, send a copy to the City radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and City requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. Kurzman at (516) 921-2035.

Sincerely yours,

Brenda J. Holman
District Director
U.S. Food and Drug Administration
New York District

BJH:mlk

cc: Jim Potter
Director, Government Relations
American College of Radiology
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Reston, VA 22091

cc: Dorothy Pender
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